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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/496,444 | 02/02/2000 | Yumin Tao | 1109 | 6243 |

27310 7590 09/20/2002

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EXAMINER

COLLINS, CYNTHIA E

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1638

DATE MAILED: 09/20/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/496,444

Applicant(s)

TAO ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-18, 22-25, 27-53 and 64-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22, 65, 70 and 75 is/are allowed.
- 6) ☒ Claim(s) 2-18, 23-25, 27-53, 64, 66-69, 71-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

The Amendment filed June 25, 2002, paper no. 22, has been entered.

Claims 2-18, 22-25, 27-53, and 64-75 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed January 14, 2002, Paper No. 18, is attached to the instant Office action.

Claim Rejections - 35 USC § 112

Claims 2-18, 23-25, 27-53, 64, 66-69 and 71-74 remain rejected, under 35 U.S.C. 112, first paragraph, for written description, for the reasons of record set forth in the office action mailed February 25, 2002.

Applicant's arguments filed June 25, 2002, have been fully considered but they are not persuasive.

Applicant argues that an adequate written description of a claimed genus can be made via structure, and that a relatively high percent identity of a specific sequence is provided in the claims. Applicant argues that the specification does disclose how the structure of the claimed invention is correlated with cyclin E activity, and points to page 6 of the specification, where a cyclin E polynucleotide is defined as encoding a polypeptide that binds to cdk2 and Rb proteins, as containing a cyclin box, and as containing the conserved TTPXS motif near the carboxy-terminus. Applicant points out that the disclosed maize cyclin E polynucleotide contains a Cdk2

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phosphorylation site that is a well known cyclin E functional motif and diagnostic of cyclin E, and that the disclosed maize cyclin E polynucleotide has high homology in the highly conserved and well known cyclin box (reply page 2).

The Examiner maintains that an adequate written description of a claimed genus requires a description of both a structure and a function that is correlated with it. While claim 64 recites a specific percent identity (80%) of a specific nucleic acid sequence (SEQ ID NO:1), a specific function correlated with a plant cyclin E polynucleotide having at least 80% identity to SEQ ID NO:1 is not recited. Furthermore, while the specification does disclose that a cyclin E polynucleotide is defined as encoding a polypeptide that binds to cdk2 and Rb proteins, as containing a cyclin box, and as containing the conserved TTPXS motif near the carboxy-terminus, the specification does not disclose whether nucleic acid sequences having at least 80% identity to SEQ ID NO:1 and having the structural elements of a cyclin box and a conserved TTPXS motif near the carboxy-terminus would encode cyclin E proteins that could be used to practice the claimed invention. The Examiner does not dispute that the isolated nucleic acid of SEQ ID NO:1 has the structural and functional characteristics of a nucleic acid encoding a functional cyclin E protein, but the rejected claims are not limited the isolated nucleic acid of SEQ ID NO:1, or to isolated nucleic acids encoding a functional cyclin E protein.

Claims 2-18, 23-25, 27-53, 64, 66-69 and 71-74 remain rejected, under 35 U.S.C. 112, first paragraph, for enablement, for the reasons of record set forth in the office action mailed February 25, 2002.

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Applicant's arguments filed June 25, 2002, have been fully considered but they are not persuasive.

Applicant argues that the specification provides not only the full length polynucleotides of the present invention, but also guidance on making modifications and variants, as well as methods to identify compositions and assays to determine their functionality. Applicant argues that the requirement for assaying does not mean the invention is not enabled, and that testing to determine functionality is routine. Applicant argues that in addition to methods for altering codon usage, the specification provides other methods, such as methods for finding functional variants by hybridization, oligonucleotide-directed mutagenesis, linker-scanning mutagenesis and mutagenesis by PCR. Applicant argues that the specification enables the scope of the invention, as Applicant has provided both a correlation between cyclin E structure and function, as well as various ways to find variants of or modify the cyclin E sequence (reply page 3).

The Examiner maintains that the specification does not disclose modifications or variants of SEQ ID NO:1. The Examiner also maintains that the disclosure of methods to identify compositions and assays to determine their functionality does not provide sufficient guidance for one skilled in the art to determine, without undue experimentation, which isolated nucleic acids encode a protein that could be used to practice the claimed invention, as the specification does not disclose whether nucleic acid sequences having at least 80% identity to SEQ ID NO:1 and having the structural elements of a cyclin box and a conserved TTPXS motif near the carboxy-terminus would encode cyclin E proteins that could be used to practice the claimed invention. Likewise, The Examiner maintains that the disclosure of methods for finding functional variants

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by hybridization, oligonucleotide-directed mutagenesis, linker-scanning mutagenesis and mutagenesis by PCR does not provide sufficient guidance for one skilled in the art to determine, without undue experimentation, which isolated nucleic acids encode a functional protein, as the specification does not disclose whether nucleic acid sequences having at least 80% identity to SEQ ID NO:1 and having the structural elements of a cyclin box and a conserved TTPXS motif near the carboxy-terminus would encode cyclin E proteins that could be used to practice the claimed invention. The Examiner maintains that the undue experimentation lies in the process of selecting from among the numerous isolated nucleic acids having at least 80% identity to SEQ ID NO:1 those that would encode a cyclin E protein that could be used to practice the claimed invention, as the claimed invention not limited to isolated nucleic acids encoding functional cyclin E proteins, but is directed also to methods whose results are highly unpredictable.

Claim Rejections - 35 USC § 101

Claims 16-18 remain rejected under 35 U.S.C. 101 as not being supported by a specific and substantial utility. for the reasons of record set forth in the office action mailed February 25, 2002.

Applicant's arguments filed June 25, 2002, have been fully considered but they are not persuasive.

Applicant points to page 12 of the specification and argues that overexpression of cyclin E genes can stimulate the endoreduplication process in plants, and that cyclin E mediated stimulation of cell division could lead to increased growth of tissues and could increase crop yield, growth and biomass (reply page 3). Applicant argues that this constitutes a specific and

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substantial utility, and that the Examiner has not cited anything that would discredit the these utilities (reply page 4).

The Examiner maintains that the effect of overexpressing a nucleic acid encoding a cyclin E protein in a transgenic plant is not a well-established utility, and that because the effect of overexpressing a nucleic acid encoding a cyclin E protein on the phenotype of a transgenic plant is highly unpredictable, the utilities that are asserted in the specification are not specific and substantial in the absence of evidence that the claimed transgenic plants and seed have some specific and substantial utility relative to nontransformed plants.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Remarks

Claims 2-18, 23-25, 27-53, 64, 66-69 and 71-74 are rejected.

Claims 22, 65, 70 and 75 are allowable.

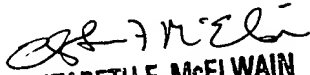
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210.

The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
September 18, 2002


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800